

Remarks

In view of the above amendments and the following remarks, reconsideration and further examination are requested.

The specification and abstract have been reviewed and revised to make a number of editorial revisions. A substitute specification and abstract have been prepared and are submitted herewith. No new matter has been added. Enclosed is a marked-up copy of the specification and abstract indicating the changes incorporated therein.

In addition, claims 1, 2, 4-7, 9-12, 14 and 15 have been amended to make a number of editorial revisions. These revisions have been made to place the claims in better U.S. form. None of these amendments have been made to narrow the scope of protection of the claims, nor to address issues related to patentability and therefore, these amendments should not be construed as limiting the scope of equivalents of the claimed features offered by the Doctrine of Equivalents.

Claims 6-10 have been rejected under 35 U.S.C. §101 as being directed to nonstatutory subject matter. Specifically, the rejection indicates that the method only relates to the manipulation of numbers and relies on the holding in In re Rex D. Schrader and Eugene D. Klingaman, 22 F.3d 290 (1994), in determining that the claim is nonstatutory. This rejection under 35 U.S.C. §101 is respectfully traversed for the following reasons.

It is first noted that the present situation appears to be directly related to the Federal Circuit case of State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (1998) (hereinafter State Street), which is the leading case regarding the present issue. As a result, a copy of the State Street decision is included herewith for the Examiner's review.

State Street outlines the determination as to whether or not an invention is directed to statutory subject matter. Initially, State Street reiterates that an invention is patentable under 35 U.S.C. §101 if it falls into one of the four enumerated categories of statutory subject matter, including a machine or a process. (See State Street, 1372). State Street also discusses the two judicially-created exceptions to statutory subject matter, the "mathematical algorithm" exception and the "business method" exception.

With regard to the “mathematical algorithm” exception, on which the present rejection of claim 6 relies, State Street states that the Supreme Court has identified three categories of subject matter as being unpatentable. These three categories are laws of nature, natural phenomena, and abstract ideas. State Street then details that in the case of Diehr, 450 U.S. 175 (1978), the Supreme Court explained that certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application, i.e., “a useful, concrete and tangible result.” State Street expands on this concept and indicates that unpatentable mathematical algorithms are identifiable by showing that they are merely abstract ideas constituting disembodied concepts or truths that are not “useful.” In other words, State Street indicates that in order for an algorithm to be patentable, it must be applied in a “useful” way. To this end, State Street held that the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price constitutes a practical application of a mathematical algorithm, formula or calculation, because it produces “a useful, concrete and tangible result,” a final share price momentarily fixed for recording and reporting purposes. (See State Street, 1373).

In applying the “useful, concrete and tangible result” test of State Street to the invention of claim 6, it is apparent that claims 6-10 represent statutory subject matter. That is, even if the setting and judging operations of claim 6 are deemed to represent a mathematical algorithm, the operation of acquiring numerical data from a measuring area when the measuring area is judged to meet a condition and the operation of changing a position of the measuring area with regard to a biological sample when the measuring area is judged not to meet the condition clearly show that the claim has a practical application because a useful, concrete and tangible result of either acquiring the numerical data or changing the position of the measuring area is dependent on whether the measuring area meets the condition.

Further, it is noted that State Street provides a brief discussion of the *Freeman-Walter-Abele* test used in Schrader (cited in the rejection) and indicates that it has little, if any, applicability to determining the presence of statutory subject matter. State Street continues stating that application of the *Freeman-Walter-Abele* test “could be misleading, because a process, machine, manufacture, or composition of matter employing a law of

nature, natural phenomenon, or abstract idea is patentable subject matter even though a law of nature, natural phenomenon, or abstract idea would not, by itself, be entitled to such protection.” Further, State Street states that “the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, of course, its operation does not produce a ‘useful, concrete and tangible result.’” (See State Street, 1374-1375).

Based on the above discussion, it is apparent that the rejection under 35 U.S.C. §101 of claims 6-10 is improper and withdrawal of the rejection is respectfully requested.

Claims 1-15 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the rejection indicates that claims 1, 2, 4-7, 9-12, 14 and 15 contain a number of vague terms and phrases. Claims 1, 2, 4-7, 9-12, 14 and 15 have been amended so as to replace these terms and phrases with define language. As a result, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-4, 6-9, and 11-14 have been rejected under 35 U.S.C. §102(b) as being anticipated by Wilhelm (US 5,715,327). Claims 1-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wilhelm in view of Sammack (US 2001/0041347). These rejections are respectfully traversed for the following reasons.

Claim 1 is patentable over Wilhelm and the combination of Wilhelm and Sammack, since claim 1 recites an evaluation apparatus having, in part, a measuring area changing unit for changing a position of a measuring area with regard to a biological sample when a condition pass/fail determining unit determines a predetermined condition is not met. Neither Wilhelm nor the combination of Wilhelm and Sammack discloses or suggests a measuring area changing unit as recited in claim 1.

Wilhelm discloses an apparatus for determining whether a slide is suitable for processing. The apparatus has an imaging system 502, a motion control system 504, an image processing system 536, a central processing system 540, and a workstation 542. The imaging system 502 includes an illuminator 508, imaging optics 510 including an automated microscope 511, a CCD camera 512, an illumination sensor 514, and an image capture and focus system 516. The motion control system 504 has a tray handler 518, a

microscope stage controller 520, a microscope stage controller 522, a calibration slide 524, and motor drivers 526 for positioning a slide under the optics 510. (See column 3, line 47 – column 4, line 10 and Figures 1A and 1B).

During slide suitability testing, the central computer 540 controls the microscope 511 and acquires and digitizes images from the microscope 511. The central computer 540 also controls the microscope stage to position the specimen under the microscope objective, and one to fifteen field of view processors 568 which receive images under control of the computer 540. The processor 540 computes a suitability score that indicates whether a slide passed or failed each of thirteen suitability tests. The suitability score detects conditions under which an automated screener will have performance limitations. In order to pass and be suitable for reporting results, the slide must pass all thirteen tests. If the slide fails, the first failed test is identified. (See column 4, line 23 – column 5, line 27).

With regard to the thirteen tests, one of the tests is based on the percentage of a first scan list of $20\times$ images acquired in focus on the first try. During $20\times$ acquisition, the system software acquires an image and then checks how well the image was focused. If the image was not focus well enough, another attempt at acquisition is made. (See column 7, lines 44-50).

Based on the above discussion, Wilhelm discloses that (1) the motion control system 504 is capable of moving the slide under the optics 510, (2) if any of the suitability scores of the thirteen tests of the slide are unsuitable, the slide is not used, and (3) if an image from the slide is not sufficiently focused, another attempt at image acquisition is attempted. However, Wilhelm fails to disclose or suggest that the motion control system 504 changes a position of a measuring area with regard to a biological sample on the slide when one of the suitability scores is insufficient. As a result, Wilhelm fails to disclose or suggest the present invention as recited in claim 1.

As for the combination of Wilhelm and Sammack, Sammack discloses a system for cell screening that utilizes operator-directed parameters. In the system, the user specifies which wells of a plate the system will scan and how many fields or how many cells to analyze in each of the wells 100. During an automated scan, the system dynamically displays the scan status, including the number of cells analyzed, the current

well being analyzed, images of each independent wavelength as they are acquired, and the result of a screen for each well as it is determined. The user also presets morphological selection criteria by either typing known cell morphological features into the system or by using an interactive training utility in the system. If objects of interest are found by the system, each object of interest is located in the image for further analysis 110. Further, after measuring all cell features 112, the system checks for any unprocessed objects in the current field 113. If no unprocessed objects exist, the system locates the next object for analysis. (See page 8, paragraph [0097] – page 10, paragraph, 0121] and Figure 9).

Based on the above discussion, it is apparent that Sammack discloses a system where a user can specify which wells of a plate to be scanned and how many fields or how many cells to analyze in each of the wells. However, Sammack fails to disclose or suggest that the system changes a position of a measuring area with regard to a biological sample when it is determined a predetermined condition is not met. In other words, the system of Sammack is designed to scans the wells and the number of fields or cells in the wells set by the user and does not change the position of the measuring area with regard to the biological sample when the system determines that a predetermined condition is not met.

As a result, it is also apparent that the combination of Wilhelm and Sammack fails to disclose or suggest the present invention as recited in claim 1.

As for claims 6 and 11, they are patentable over Wilhelm and the combination of Wilhelm and Sammack for similar reasons as set forth above in support of claim 1. That is, claims 6 and 11, like above claim 1, recite, in part, changing a position of a measuring area with regard to a biological sample when a measuring area is judged not to meet a condition, which feature is not disclosed or suggested by the references.

Because of the above mentioned distinctions, it is believed clear that claims 1-15 are allowable over the references relied upon in the rejections. Furthermore, it is submitted that the distinctions are such that a person having ordinary skill in the art at the time of invention would not have been motivated to make any combination of the references of record in such a manner as to result in, or otherwise render obvious, the

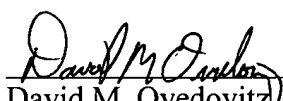
present invention as recited in claims 1-15. Therefore, it is submitted that claims 1-15 are clearly allowable over the prior art of record.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if it is felt that there are issues remaining which must be resolved before allowance of the application.

Respectfully submitted,

Kanji YAHIRO

By:


David M. Ovedovitz
Registration No. 45,836
Attorney for Applicant

DMO/jmj
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
April 13, 2004